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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,562	11/08/1999	ERIK J. VAN DER BURG	MVMDINC.001C	5387

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EXAMINER

DAWSON, GLENN K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/435,562

Applicant(s)

VAN DER BURG ET AL.

Examiner

Glenn K. Dawson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-45, 51-98, 101, 106-109 and 129-134 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 38-45, 51-98, 129 and 130 is/are allowed.
6) ☒ Claim(s) 101, 107-109 and 131-134 is/are rejected.
7) ☒ Claim(s) 106 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01-30-2006
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 101 and 107-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin, et al.-5928260 in view of Dubrul-6258115.

Chin discloses a blood filter having embodiments with proximal and distal ends separated by a middle portion forming an apex when the filter is expanded to an enlarged configuration. See fig. 14f and fig. 17. The entire device including the filter and the coaxial tubes could be separated from an outer guiding catheter and the filter could be implanted in the LAA. A proximal portion of the frame is covered by a membrane which would allow for tissue ingrowth (therefore it is an endothelialization membrane). However, the specific porosity of the membrane is not disclosed. Dubrul discloses that it was known to provide filter material having a porosity which could filter out 2-300 micron particles. It would have been obvious to have provided a filter material in the claimed porosity, as this would allow for the passage of blood therethrough and would allow for the blockage of particles in this size range which can be detrimental to a patient's health.

Claims 131-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottonceau, et al.-5375612 in view of Wnenchak, et al.-6110243.

Cottonceau discloses a blood filter having a self-expanding wire frame of linked filaments and a membrane 9 formed of an absorbable suture thread which closes off the proximal end of the filter. See fig. 15 and col. 2 lines 8-35; col. 3 lines 19-32; col. 4 lines 33-39. However, the membrane is not made out of ePTFE. Wnenchak teaches that ePTFE is a known filter material and because of its low surface energy it cleaned very easily. It would have been obvious to have used ePTFE as the material of the "spider web" membrane of Cottonceau as an obvious alternative as one skilled in the art would have recognized ePTFE to be an advantageous alternative based on its properties of biocompatibility and ability to expand and contract and would be easily cleanable for re-use in the event that the device were to be used in the short term.

2144.07 Art Recognized Suitability for an Intended Purpose

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) (Claims to a printing ink comprising a solvent having the vapor pressure characteristics of butyl carbitol so that the ink would not dry at room temperature but would dry quickly upon heating were held invalid over a reference teaching a printing ink made with a different solvent that was nonvolatile at room temperature but highly volatile when heated in view of an article which taught the desired boiling point and vapor pressure characteristics of a solvent for

Art Unit: 3731

printing inks and a catalog teaching the boiling point and vapor pressure characteristics of butyl carbitol. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.).

See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960) (selection of a known plastic to make a container of a type made of plastics prior to the invention was held to be obvious); *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) (Claimed agricultural bagging machine, which differed from a prior art machine only in that the brake means were hydraulically operated rather than mechanically operated, was held to be obvious over the prior art machine in view of references which disclosed hydraulic brakes for performing the same function, albeit in a different environment.).

Claims 131-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch-5853422 in view of Lentz, et al.-5961545.

Huebsch discloses a frame of a cylindrical configuration as shown in fig. 2(if placed into a small diameter lumen the fully expanded configuration would be substantially cylindrical), and expandable. After only a slight expansion the shape would still be relatively cylindrical. As stated in col. 7 lines 44-56, the entire device may be covered by a fabric which allows tissue ingrowth. However, the material being ePTFE is not disclosed. Lentz discloses that it was known that the internodes of ePTFE are known to encourage tissue ingrowth. It would have been obvious to have used a fabric

made out of ePTFE to cover the device of Huebsch, as it would allow for tissue ingrowth.

Allowable Subject Matter

Claims 38-45, 51-98, 129 and 130 are allowed.

Claim 106 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 11-29-2005 have been fully considered but they are not persuasive.

Applicant argues that the device of Chin is not adapted to be separated from a delivery device because this feature is not stated. However, for a product to meet a functional or intended use limitation, it only need be capable of performing the function. If the prior art device is capable of being separated from a delivery device, then it meets the claim limitations. Clearly, the entire device of Chin could be placed into a guiding catheter, and removed therefrom and deployed into an LAA.

Applicant also argues that there is no teaching or suggestion to combine Cottonceau and Wnenschak, and there is no reasonable expectation of success. The examiner disagrees. It has long been established that merely exchanging one material for another based on the material's suitability for its intended purpose is motivation for making a modification of the manufacturing material of a product.

EPTFE is a known material generally used in filters and which possesses the required characteristics of biocompatibility and flexibility necessary to function as a worthy substitute for the material disclosed by Cottonceau. The e-PTFE could either be used as a sheet using the internodal interstices to allow for passage of blood therethrough, or the individual fibers making up the filter could be made out of e-PTFE. The examiner contends that since the material of the applicant's device need not even be ePTFE, that it is really not a critical aspect of applicant's invention. Lacking criticality, and because the prior art material would seem to perform equally as well, the substitution of e-PTFE for the filter material for Cottonceau would have been obvious. Additionally, since e-PTFE would have the necessary characteristics, there would be every reason to conclude that the filtering device of Cottonceau would perform well with e-PTFE as the filtering material. If left in place long enough, virtually any porous material would act as an endothelialization membrane.

As noted above the device of Huebsch would attain a substantially cylindrical configuration when maximally expanded into a lumen of a size only slightly larger in diameter than itself.

Since the covering of Huebsch is to allow tissue ingrowth, and because e-PTFE was known to have allowed tissue in-growth, the use of e-PTFE as the covering for Huebsch's device is considered obvious, and there would be every reason to assume success when using this material based on it's characteristics.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
14 February 2006